R. Michael Crompton, JD, MPH
Curriculum Vitae

1. Date: June 2, 2003

PERSONAL

2. Name, Title, and Business Address:

R. Michael Crompton, JD, MPH
Vice President, Regulatory / Clinical Affairs
and Quality Assurance
Carl Zeiss Meditec, Incorporated
5160 Hacienda Drive
Dublin, California 94568

3. Office Phone, Fax, and e-mail:

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HIGHER EDUCATION

4. Institutional:

Doctor of Jurisprudence
University of San Francisco School of Law
San Francisco, California

Masters Degree: Public Health (Biomedical Sciences)
University of California, Berkeley
Berkeley, California

Bachelors Degree: Biochemistry
University of California, Berkeley
Berkeley, California

5. Non-Institutional: None

6. Professional Licenses and Certifications:

Member, The State Bar of California

PROFESSIONAL EXPERIENCE

7. FDA-regulated Entities and Related Concerns

Vice President, Regulatory / Clinical Affairs and Quality Assurance — 10/2002 – present
Carl Zeiss Meditec, Incorporated
Dublin, California

Provide executive leadership for Regulatory Affairs, Clinical Affairs, and Quality Assurance activities for developer, manufacturer, and distributor of class I, class II and class III ophthalmic diagnostic and treatment medical devices.

Vice President, Regulatory / Clinical Affairs and Quality Assurance — 12/2000 – 09/2002
CryoVascular Systems, Incorporated
Los Gatos, California

Provided executive leadership for Regulatory Affairs, Clinical Affairs, and Quality Assurance activities world-wide for developer of novel, class II and class III, cryotherapeutic medical devices for vascular and cardiovascular applications.

Vice President, Regulatory Affairs & Quality Assurance — 1996 – 11/2000
Vice President, Clinical Affairs (interim) — 01/1997 – 10/1997
Symphonix Devices, Incorporated
San Jose, California

Provided executive leadership for Regulatory Affairs and Quality Assurance activities world-wide for developer and manufacturer of novel, class III, active implantable medical device for the hearing impaired. Responsibilities included sponsor-related activities to achieve the first FDA approval and first CE Mark authorization for an implantable middle ear hearing device for the treatment of sensorineural hearing loss.

Senior Director of Regulatory Affairs — 1995 – 05/1996
Director of Regulatory Affairs — 1991 - 1992
Senior Regulatory Professional — 1993 - 1994
Advanced Bioresearch Associates
Danville, California and
Rockville, Maryland

Prepared and reviewed FDA submissions [PMAs, 510(k)s, IDEs, BLAs] and international product registration dossiers. Drafted policies and procedures to assist clients in attaining regulatory compliance. Conducted facility audits for conformance to Quality System Regulation / cGMPs / EN ISO 9001 / EN 46001 requirements.

Attorney 1994 – 1995
Hyman, Phelps & McNamara, PC
Washington, DC

Counseled clients on rights and responsibilities under the Federal Food, Drug, and Cosmetic Act and related statutes, with specific emphasis on regulations regarding medical devices, biologics, and combination products.

Manager of Regulatory Affairs 1992 - 1993
TOSOH MEDICS, Incorporated
Foster City, California

Managed FDA approval of three premarket approval applications and facilitated FDA clearance of 16 510(k) premarket notifications for novel clinical chemistry analyzers and *in vitro* diagnostic devices.

Project Administrator / Project Analyst 1983 - 1991
Immunoproduction Supervisor
Chemist I, Chemist II, Chemist III
Syva Company / Syntex Corporation
Palo Alto and Cupertino, California

Drafted 510(k) premarket notifications. Reviewed labeling and promotional materials for regulatory compliance. Supervised technical professionals in GMP manufacturing environment. Developed powder-formulated assays for novel *in vitro* diagnostics for therapeutic drug monitoring and drugs of abuse tests.

PROFESSIONAL ASSOCIATIONS

8. FDA-related Associations:

American Society for Quality; Milwaukee, Wisconsin

Regulatory Affairs Professionals Society; Rockville, Maryland

Silicon Valley Biomedical Council; Santa Clara, California

The State Bar of California; San Francisco, California

PRESENTATIONS AND PUBLICATIONS

9. FDA-related Presentations and Publications:

Hot Topics: PMAs. 2003 Medical Device Conference & Tabletop Exhibition. Regulatory Affairs Professionals Society. San Francisco, California. March 4, 2003.

Hot Topics: 510(k)s. 2002 Medical Device Conference & Tabletop Exhibition. Regulatory Affairs Professionals Society. San Francisco, California. March 5, 2002.

Design Controls and IDE Regulations. 43rd Educational Conference. Food and Drug Law Institute. Washington, D.C. December 16, 1999.

Investigational Device Exemptions. Introduction to Medical Device Law and Regulation. Food and Drug Law Institute. San Francisco, California. September 23-24, 1999.

Proactive Planning to Prepare a Growing Company for QS Regulation Compliance. Medical Device Design Controls & Process Validation (2nd Annual). Institute for International Research. San Diego, California. November 4, 1998.

The Role of the FDA in the Product Development Process. Introduction to Clinical Research. Ohlone College. Newark, California. September 23, 1998.

Corrective and Preventive Action Systems. The Quality System Regulation . . . A Year Later. Food and Drug Law Institute. Anaheim, California. May 18, 1998.

Perspective on Management Reviews. The Silver Sheet. 1:8 MDDI 1997:20.

Medical Device Reporting (MDR). Introduction to Medical Device Law and Regulation. Food and Drug Law Institute. San Francisco, California. September 12, 1997.

FDA/CDRH Downlink Panelist. Design Controls for Medical Devices. Food and Drug Administration, Office of Compliance, Center for Devices and Radiological Health. Rockville, Maryland. January 17, 1997.

FDA/CDRH Downlink Panelist. The Quality System Regulation. Food and Drug Administration, Office of Compliance, Center for Devices and Radiological Health. Rockville, Maryland. September 20, 1996.

Crompton, RM. *Raising the Standard – FDA's New Guidance for IVDs*. 4 In Vitro Tech 1995:48.

Crompton, RM. *Corporate Structure and GMP Compliance*. 16 Med Dev Diag Ind 1994:80.

REFERENCES

10. Professional:

Available upon request.

11. Personal:

Available upon request.